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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---------------------------------|------------------------------|---------------------|------------------|
| 10/598,280 | 06/12/2007 | Mark Samuel Beaton McAlister | 101411-1P US | 2272 |
| | 7590 12/09/200 CA R&D BOSTON | | EXAMINER | |
| 35 GATEHOUS | SE DRIVE | | SINGH, SATYENDRA K | |
| WALTHAM, MA 02451-1215 | | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/09/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|-----------------------|--|--|--|--|
| Office Action Comments | 10/598,280 | MCALISTER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | SATYENDRA K. SINGH | 1657 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 23 A | uaust 2006. | | | | | |
| · <u> </u> | action is non-final. | | | | | |
| , <u> </u> | _ | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 1-32 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-32 are subject to restriction and/or expressions. | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ acc | 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) M Notice of References Cited (PTO-892) | 4) 🔲 Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | atent Application | | | | | |

Application/Control Number: 10/598,280 Page 2

Art Unit: 1657

DETAILED ACTION

Applicant's claim amendment filed on 08/23/2006 is duly acknowledged.

Claims 1-32 (as amended) are currently pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-26, drawn to a method for preparing a soluble protein comprising a modified form of urokinase-type plasminogen activator (uPA) or an active fragment thereof, or a variant of either of these which has uPA activity (see claim 1, in particular).

Group II, claim(s) 27-29 and 32, drawn to a soluble protein comprising modified uPA or an active fragment, or variant of any of these which has uPA activity, obtainable by the method of group I (see claim 27, in particular).

Group III, claim(s) 30-31, drawn to a method for identifying ligands for uPA as specifically recited in claim 30.

NOTE: It is noted that applicants have presented **claim 32** in the format of a "**use claim**", which is improper. For the purposes of this office action, claim 32 has been taken as a product claim (i.e. the product of group II, that can be used for X ray crystallographic applications) and grouped with the product of group II. Applicants are advised to appropriately amend the claim 32 in order to clarify the subject matter being claimed in response to this office action.

2. The inventions listed as Groups (I-III) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical

Art Unit: 1657

feature of the invention as claimed is the product (i.e. "a soluble protein comprising modified uPA or an active fragment, or variant of any of these which has uPA activity"; see claim 27, in particular) recited in claim 27-29 and 32 (i.e. group II), which has been fully disclosed in the cited prior art reference of **ZESLAWSKA et al** (2000; [U]; see title, abstract, Materials & Methods, figure 1 and table 3, in particular), and thus the invention as claimed lacks unity under PCT Rule 13.2.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 4. The examiner has required restriction between **product and process claims**.

 Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

Application/Control Number: 10/598,280

Art Unit: 1657

require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

Page 4

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/598,280 Page 5

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/ Primary Examiner, Art Unit 1651

/Satyendra K. Singh/ Examiner, Art Unit 1657